

Notice of Allowability

Application No.

10/757,810

Examiner

Amelia A. Owens

Applicant(s)

WENDER ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response filed 3/15/2006.
2. ☒ The allowed claim(s) is/are 2-48 and 50-58.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other Drawings OK

1-13-04 WAS

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

1. Claims 2-48,50-58 are pending and are allowed.
2. The rejection of claims 2-5,54-57 under 35 USC 112, 1st paragraph has been dropped as the claims have been amended.
3. USP 6548485 B2 (already of record) teaches apoptolidin derivatives to treat tumors. See column 1 lines 35-58. Salmon et al (already of record), Understanding and exploiting the mechanistic basis for selectivity of polyketide inhibitors of F₀F₁-ATPase, PNAS, 97(26), pp.14766-14771, December 19, 2000, teach apoptolidin induces apoptosis in cells. See abstract, page 14766 column 1 lines 1-20. Structurally similar compounds would be expected to have similar properties. Thus, the one of ordinary skill in the art would expect the claimed apoptolidin and isoapoptolidin compounds to induce apoptosis in cancer cells.

The data in the specification in example 5/Table 5 is noted. The compounds inhibit F₀F₁-ATPase as does apoptolidin.

4. Claim 16 provisos out apoptolidin and therefore distinguishes over the art. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.
5. Claim 26, position Q9 is different than for the Pennington et al reference, Organic Letters, 4(22) pp 3823-3825, (2002), thereby distinguishing over the art. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.
6. Claim 26 differs from claim 1 of USP 6548485 B2 in that the claimed ring is 21members and the reference compound has 20 ring members; also the claimed compound has -OQ2 variable at position 23. Motivation is lacking to modify the reference to arrive at the claimed compound.
7. Claim 51 has a benzopyrrole fused to the core apoptolidin ring at positions 10-13 thereby distinguishing over the apoptolidin compounds. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.
8. The prior art neither teaches nor suggests the claimed compounds. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal et al, 158 USPQ 320; Ex parte Krenzer, 199 USPQ 227.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Amelia A. Owens
Primary Examiner
Art Unit 1625